IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
CHATTANOOGA DIVISION

VERONICA RYAN, ***Plaintiff,*** **v.** **JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC; JOHNSON & JOHNSON CO.; JANSSEN ORTHO LLC; MITSUBISHI TANABE PHARMA HOLDINGS AMERICA, INC.; MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC.; TANABE RESEARCH LABORATORIES, U.S.A., INC., and MITSUBISHI TANABE PHARMA CORP.,** ***Defendants.***	**Case No.: 1:16-cv-00407** **AMENDED COMPLAINT WITH DEMAND FOR JURY TRIAL**

COMES NOW, the Plaintiff, VERONICA RYAN, by and through the undersigned attorneys, and hereby brings the following allegations and causes of action against the Defendant.

AMENDED COMPLAINT

1. Plaintiff Veronica Ryan (hereinafter Plaintiff), complaining against Defendants, Janssen Research & Development, LLC; Janssen Pharmaceuticals, Johnson & Johnson, Janssen Ortho, LLC, Mitsubishi Tanabe Pharma Holdings America, Inc., Mitsubishi Tanabe Pharma

Development America, Inc., Tanabe Research Laboratories U.S.A., Inc., and Mitsubishi Tanabe Pharma Corp. state as follows:

BACKGROUND

2. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Invokana (also known as canagliflozin).

PARTIES

3. At the time of Plaintiff Veronica Ryan's use of Invokana and injuries, Plaintiff was a resident and citizen of Chattanooga, Hamilton County, Tennessee. Plaintiff presently is a citizen of and resides in Chattanooga, Hamilton County, Tennessee.

4. Defendant Janssen Research & Development LLC (Janssen R&D) is a limited liability company organized under the laws of New Jersey, with a principal place of business at 920 Route 202, Raritan, New Jersey 08869. Janssen R&D's sole member is Janssen Pharmaceuticals, Inc.

5. Janssen R&D is registered to do business throughout the United States, including in Tennessee, the state where Plaintiff resides and was treated.

6. Defendant Janssen Pharmaceuticals, Inc. (Janssen) is a Pennsylvania corporation with a principal place of business at 800 Ridgeview Drive, Horsham, Pennsylvania 19044. Both Janssen, and its wholly owned LLC, Janssen R&D, are subsidiaries of Johnson & Johnson.

7. Janssen is registered to do business throughout the United States, including in Tennessee, the state where Plaintiff resides and was treated.

8. Defendant Johnson & Johnson, Inc. (J&J) is a New Jersey corporation with a

principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. J&J is registered to do business throughout the United States, including in Tennessee where Plaintiff resides and was treated.

10. Defendant Janssen Ortho, LLC, (Janssen Ortho) is a Delaware company with a principal place of business at State Road 933 Km 01, Gurabo, Puerto Rico 00778.

11. Janssen Ortho is registered to do business throughout the United States, including Tennessee where Plaintiff resides and was treated.

12. At all relevant times, Janssen Ortho manufactured Invokana.

13. Defendant Mitsubishi Tanabe Pharma Corp. (Tanabe) is a Japanese corporation with its principal place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan. Tanabe is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana.

14. Defendant Mitsubishi Tanabe Pharma Holdings America, Inc. (Tanabe Holdings) is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, New Jersey 07310.

15. Tanabe Holdings is a subsidiary of Tanabe and a holding company for U.S. subsidiaries.

16. Defendant Mitsubishi Tanabe Pharma Development America, Inc. (Tanabe Development) is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, New Jersey 07310.

17. Tanabe Development licenses pharmaceuticals and drug therapies including Invokana for its parent corporation, Tanabe and conducts clinical development activity for obtaining marketing approval of drugs in the U.S., including Invokana, and provides administration support for the U.S. affiliates.

18. Defendant Tanabe Research Laboratories U.S.A., Inc. (Tanabe Research) is a California corporation, with a principal place of business 4540 Towne Centre Court, San Diego, California 92121.

19. Tanabe Research conducts pharmaceutical research, including with respect to Invokana.

20. At all times herein mentioned, Defendants advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, Invokana.

JURISDICTION AND VENUE

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal place of business in states other than the state in which Plaintiff is a citizen.

22. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants' conduct substantial business in this District.

23. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including Invokana, within Tennessee, with a reasonable expectation that the products

would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

24. At all times relevant to this action, Defendants were engaged in substantial business activities in Tennessee, including disseminating inaccurate, false, and misleading information about Invokana to health care professionals in Tennessee, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout Tennessee and throughout the United States.

25. At all times relevant to this action, Defendants were registered to do business in Tennessee.

26. At all times relevant to this action, Defendants consented to jurisdiction of this Court.

FACTUAL ALLEGATIONS

27. This action is for damages brought on behalf of the Plaintiff. Veronica Ryan was prescribed and supplied with, received and has taken the prescription drug Invokana. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering severe and life-threatening side effects of diabetic ketoacidosis ("DKA"), caused by this drug.

28. Invokana is a member of the gliflozin class of pharmaceuticals, also known as sodium-glucose co-transporter 2 ("SGLT2") inhibitors.

29. SGLT2 inhibitors, including Invokana, inhibit renal glucose reabsorption through the SGLT2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract. This puts additional stress on the kidneys in patients already at risk for kidney disease.

30. SGLT2 inhibitors, including Invokana, are designed to target primarily the SGLT2 receptor, but have varying selectivity for this receptor, and block other sodium-glucose co- transporter receptors, including SGLT1.

31. The SGLT2 and SGLT1 receptors are located throughout the body, including in the kidney, intestines, and brain.

32. Invokana has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States.

33. SGLT2 inhibitors, including Invokana, are currently approved only for improvement of glycemic control in adults with type 2 diabetes.

34. At all times herein mentioned, the Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Invokana for the use and application by patients with diabetes, including, but not limited to, Plaintiff.

35. On information and belief, Defendants Tanabe, Tanabe Holdings, Tanabe Development, and Tanabe Research, in collaboration with the other Defendants, designed developed, and marketed the diabetes drug, Invokana in the United States, and have made misrepresentations regarding the safety of the drug.

36. Defendant J&J, the parent company of Janssen, is involved in the marketing and branding of Invokana and publishes marketing and warnings regarding the product.

37. Indeed, Defendants have published advertisements on their company websites and issued press releases announcing favorable information about Invokana. For example, the FDA's approval of Invokana on March 29, 2013 was announced on the J&J web site. On April 1, 2013,

Tanabe announced the approval of Invokana in the United States as a new treatment option for Type 2 diabetes. On March 14, 2016, the J&J issued a press release announcing "First Real-World Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Shows Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (canagliflozin)". The former announcements did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions.

38. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities at residents of Tennessee.

39. The Invokana-related pages on the Defendants' web sites are accessible from within Tennessee, and have been indexed by search engines so that they are located through searches that are conducted from within Tennessee.

40. Defendant J&J also published information touting the strong sales of Invokana in its corporate reports and in earnings calls.

41. Further, J&J employees had responsibility for overseeing promotion strategies for the drug Invokana.

42. All marketing materials, advertisements, press releases, web site publications, dear doctor letters, and other communications regarding Invokana are part of the design and labeling of the drug, and could be altered without prior FDA approval.

43. Defendant J&J had the ability and the duty to independently alter the design and labeling of Invokana. Specifically, it could independently publish additional warnings regarding Invokana, particularly the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infection, bone fracture, etc.

44. Defendant J&J so substantially dominates and controls the operations of Janssen,

Janssen R&D, and Janssen Ortho, that it could have required them to make changes to the safety label of the drug Invokana.

45. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokana and direct these activities on behalf of J&J, Janssen, Janssen R&D, and Janssen Ortho.

46. In fact, J&J so substantially dominates and controls the operations of Janssen, Janssen R&D, and Janssen Ortho, that the entities are indistinct for purposes of this litigation such that Janssen, Janssen R&D, and Janssen Ortho should be considered agents or departments of J&J, and J&J is their alter-ego.

47. Employees of Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokana and direct these activities on behalf of J&J, Janssen, Janssen R&D, and Janssen Ortho.

48. On information and belief, Defendant Janssen Ortho failed to properly manufacture Invokana to ensure consistent quality with each batch that matched the (flawed) design specifications. The failure of consistent manufacture stemmed from faulty manufacturing processes, sub-par raw materials, and failure to properly clean and maintain equipment and other manufacturing facilities to ensure no cross-contamination from microbes and cleaning products.

49. On information and belief, manufacturing defects contributed to and caused injuries described elsewhere in this amended complaint.

50. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing rights to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in the United States, including in Tennessee.

51. In May, 2012, Janssen R&D submitted a New Drug Application to the FDA for approval to market Invokana in the United States.

52. In March 2013, the FDA approved Invokana as an adjunct to diet and exercise for the improvement of glycemic control in adults with the treatment of type 2 diabetes.

53. As part of its marketing approval of Invokana, the FDA required the defendants to conduct five post-marketing studies: a cardiovascular outcomes trial; an enhanced pharmacovigilance program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamic study and a safety and efficacy study.

54. In an effort to increase sales and market share, Defendants have aggressively marketed and continue to aggressively market Invokana to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in type 1 diabetics.

55. Defendants also, through their marketing materials, misrepresented and exaggerated the effectiveness of Invokana, both as to its ability to lower glucose, and its benefit for non- surrogate measures of health, such as reducing adverse cardiovascular outcomes.

56. Defendants' marketing campaign willfully and intentionally misrepresented the risks of Invokana and failed to warn about the risks of diabetic ketoacidosis, kidney failure, and cardiovascular injury.

57. Defendants' misrepresentations and off-label advertising campaigns have led to Invokana being prescribed for off-label uses, in people with type 1 diabetes, for weight loss, and

reduced blood pressure.

58. Invokana is one of Defendants' top selling drugs, with annual sales exceeding $1 billion.

59. At all times herein mentioned, Defendants were authorized to do business within Tennessee.

60. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

61. Defendants, both individually and in concert with one another, misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, as well as serious cardiovascular problems.

62. Specifically, Defendants knew or should have known of the risks of diabetic ketoacidosis and kidney failure based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports, and regulatory authority investigations, including, but not limited to the following:

a. Invokana selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given Invokana;

c. Studies of phlorizin indicating a propensity to cause ketoacidosis;

d. Reports involving people with familial glycosuria, indicating a propensity to develop ketoacidosis;

e. Clinical studies demonstrating increases in glucagon in people taking Invokana;

f. Clinical studies, adverse event reports, and case reports demonstrating increased ketones in people taking Invokana;

g. Clinical studies, adverse event reports, and case reports demonstrating dehydration and volume depletion in people taking Invokana;

h. Clinical studies, adverse event reports, and case reports demonstrating vomiting in people taking Invokana;

i. Clinical studies, adverse event reports, and case reports demonstrating re-challenge responses in increasing ketones and diabetic ketoacidosis in people taking Invokana; and

j. Adverse event report analysis demonstrating an increased rate of reports for ketoacidosis in people taking Invokana compared to other glucose-lowering medications.

63. Diabetic ketoacidosis may lead to complications such as cerebral edema, pulmonary edema, cerebrovascular accident, myocardial infarction, nonspecific myocardial injury, severe dehydration, and coma.

64. Invokana-induced diabetic ketoacidosis may lead to delayed treatment because in many cases Invokana will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis. This may result in increased progression of the condition and

increased injury to the patient.

65. Defendants were aware that the mechanism of action for Invokana places extraordinary strain on the kidneys and renal system.

66. Despite its knowledge of data indicating that Invokana use is causally related to the development of diabetic ketoacidosis and kidney failure, Defendants promoted and marketed Invokana as safe and effective for persons such as Plaintiff throughout the United States, including Tennessee.

67. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not warn patients but instead continued to defend Invokana, mislead physicians and the public, and minimized unfavorable findings.

68. Defendants failed to adequately warn consumers and physicians about the risks associated with Invokana and the monitoring required to ensure their patients' safety.

69. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not conduct the necessary additional studies to properly evaluate these risks prior to marketing the drug to the general public.

70. Consumers of Invokana and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including diabetic ketoacidosis, kidney failure, cardiovascular problems, and the life-threatening complications thereof.

71. Consumers, including Plaintiff, have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

72. Plaintiff was prescribed Invokana by her treating physician and used it as directed.

73. Plaintiff was prescribed Invokana to improve glycemic control as an adjunct to diet and exercise on or about December 2013.

74. While taking Invokana, Plaintiff was diagnosed with diabetic ketoacidosis ("DKA") on or about October 12, 2015 as a result of treatment with Invokana, and was hospitalized at Erlanger Health System, located in Chattanooga, Tennessee.

75. As a result of her development of diabetic ketoacidosis, Plaintiff developed serious complications which required multiple days of hospitalization.

76. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

77. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

78. Defendants, both individually and in concert with one another, misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, as well as serious cardiovascular problems.

79. Plaintiff's injuries were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana. This conduct and the product defects complained

of were substantial factors in bringing about and exacerbating Plaintiff's injuries.

80. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking Invokana.

81. On information and belief, Defendants, both individually and in concert with one another, withheld material information from the FDA and misrepresented material information regarding the risks and benefits of Invokana in its communications with the FDA. These omissions and misrepresentations included failing to report instances of diabetic ketoacidosis to the FDA, failure to properly categorize adverse events in clinical trials, post-marketing trials, and obtained through its adverse event reporting system, and withholding of relevant information from pre-clinical and clinical trials.

82. On May 15, 2015 the FDA announced that SGLT2 inhibitors may lead to diabetic ketoacidosis.

83. On September 10, 2015, the FDA announced that Invokana causes premature bone loss and fractures.

84. On October 16, 2015, Health Canada, the Canadian drug regulatory authority, announced that Invokana can cause acute kidney injury.

85. On December 4, 2015, the FDA announced a label change for SGLT2 inhibitors, requiring that the label of SGLT2 inhibitors include a warning of ketoacidosis, the risk of too much acid in the blood, while taking SGLT2 inhibitors.

86. Prior to the FDA's December 4, 2015 safety announcement, Invokana's label continued to fail to warn consumers of the serious risk of developing diabetic ketoacidosis.

87. The Invokana label currently does not warn of the serious risks of developing

bone fractures and kidney injury.

88. Despite the FDA's announcements, Defendants continue to engage in aggressive direct-to-consumer and physician marketing and advertising campaigns for Invokana.

89. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied Invokana to the purchaser.

90. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that Invokana was of such a nature that it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

91. Defendants had a duty to warn Plaintiff's prescribing physicians about the risks of Invokana use, including the risk of acute kidney failure and resulting complications.

92. Had Plaintiff and her physicians known the true risks associated with the use of SGLT2 inhibitors, including Invokana, Plaintiff would not have been prescribed Invokana, and Plaintiff would not have taken Invokana or Plaintiff would have been adequately monitored for its side effects, and as a result, would not have suffered injuries and damages from using Invokana.

93. Plaintiff's prescribing and treating physicians relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff's prescribing and treating physicians directly, through print and television advertising, articles and study reports funded and promoted by Defendants, and indirectly, through other healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

94. Plaintiff relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff directly, through print and television advertising, and indirectly, through Plaintiff's healthcare providers and others who have been exposed to Defendants' claims through their comprehensive marketing campaigns.

95. Based on Defendants' direct-to-consumer advertising and Defendants' misrepresentations and omissions, Plaintiff made an independent decision to use Invokana based on the overall benefits and risks communicated by Defendants.

96. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokana's defects, and were not reasonably foreseeable to Plaintiff or Plaintiff's physicians.

97. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injury. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

98. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Invokana caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries

as her cause was unknown to her. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that she had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that the drug Invokana is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

CAUSES OF ACTION

Count One – Design Defect (Strict Liability)

99. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

100. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by Plaintiff.

101. The design defect was caused by Defendants' failure to:

a. Adequately test Invokana;

b. Develop and provide a product label and marketing materials that accurately describes the risks of and does not overstate the benefits of using Invokana;

c. Provide full, complete, and accurate information to the FDA about Invokana;

d. Adequately test and study Invokana;

e. Ensure that the benefits of Invokana outweighed the risks for people susceptible to diabetic ketoacidosis, kidney failure or other adverse effects;

f. Conduct adequate post-market surveillance; and

g. Use a safer alternative formulation.

102. The design defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

103. The design defect was such that the risks of Invokana outweighed its utility.

104. This danger was unknowable to Plaintiff and would be considered unacceptable to the average consumer.

105. There were practical and technically feasible alternative designs that would not have reduced the utility of Invokana and would not have cost substantially more to develop, including, but not limited to providing a better warning with Invokana, using an alternative diabetes treatment, or developing an SLGT2 inhibitor with a different safety profile.

106. The label is part of the design of Invokana, and therefore the design can be changed. Specifically, the label could have included a contraindication for people whose ketones increase, which would have alerted doctors and patients that the drug Invokana is not suitable for that population because the risks outweigh the benefits.

107. Defendants' defective design of Invokana was reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over

the safety and well-being of the consumers of Invokana.

108. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

109. Defendants expected and intended Invokana to reach, and it did in fact reach, Plaintiff without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

110. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known of the design defects.

111. Plaintiff and Plaintiff's physicians did not have the same knowledge or expertise as Defendants and could not have discovered any defect in Invokana through the exercise of reasonable care.

112. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained permanent injuries.

113. The defects in Invokana were substantial contributing factors in causing Plaintiff's injuries.

Count Two – Failure to Warn (Strict Liability)

114. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

115. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d and Restatement, Third, of Torts.

116. Defendants designed, developed, researched, tested, licensed, manufactured,

packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by Plaintiff. The design defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

117. Invokana's inadequate warnings rendered Invokana unreasonably dangerous and defective.

118. Defendants' defective warnings for Invokana were reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Defendants made conscious decisions not to adequately warn about risks they know or should have known about. Defendants' reckless conduct warrants an award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Invokana.

119. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

120. Defendants expected and intended Invokana to reach, and it did in fact reach, Plaintiff without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

121. Plaintiff could not have discovered the unwarned of risks of using Invokana through the exercise of reasonable care.

122. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Invokana were incomplete and inadequate.

123. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians. The warnings that were given by the Defendants were not accurate and were incomplete.

124. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take other such steps as necessary to ensure that Invokana did not cause users to suffer from unreasonable and dangerous risks.

125. Defendants knew or should have known that the limited warnings disseminated with Invokana were inadequate, but they failed to communicate adequate information on the dangers and safe use of their product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

126. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, and failure to warn Plaintiff and her physicians about the significant risks inherent in Invokana therapy, Plaintiff sustained permanent injuries.

Count Three – Negligence

127. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

128. At all times relevant times, Defendants had a duty to use reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect,

research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Invokana.

129. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Invokana to cause or increase the harm of diabetic ketoacidosis, kidney failure, cardiovascular problems, and the life threatening complications of those conditions.

130. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others when developing and selling Invokana.

131. Defendants had a duty to disclose to physicians, healthcare providers, and patients the causal relationship or association of Invokana to diabetic ketoacidosis, kidney failure, cardiovascular problems and the life threatening complications of those conditions.

132. Defendants had a duty to accurately communicate the risks and benefits of Invokana to physicians, healthcare provides, and patients.

133. As a result of the Defendants' aggressive marketing campaigns promoting off-label uses, including for type 1 diabetes, weight loss, and to improve blood pressure and kidney function, Defendants knew or should have known and expected that consumers would use Invokana for such off-label uses.

134. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including diabetic ketoacidosis, kidney failure, and cardiovascular injury, and these injuries were foreseeable.

135. Plaintiff did not know the nature and extent of the injuries that could result from Invokana and were misinformed about the benefits of Invokana and could not have discovered this information independently.

136. At all times herein mentioned, Defendants breached their duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use, and selling Invokana, and failing to adequately test and warn of the risks and dangers of Invokana.

137. Despite the fact that Defendants knew or should have known that Invokana caused unreasonable, dangerous side effects, Defendants continued to market Invokana to consumers including Plaintiff, when there were safer alternative methods available.

138. Defendants' negligence was a foreseeable and proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

Count Four – Gross Negligence

139. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

140. Defendants had a duty to provide adequate warnings and accurately describe the risks and benefits of taking Invokana.

141. Defendants breached that duty.

142. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff.

143. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk.

144. Defendants were actually subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious and deliberate disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and her healthcare providers.

145. The acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

146. Defendants, both individually and in concert with one another, intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of Invokana. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Invokana, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Invokana, despite their knowledge and awareness of these serious side effects and risks.

147. Defendants had knowledge of, and were in possession of evidence demonstrating that Invokana caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of Invokana.

148. Although Defendants knew or recklessly disregarded the fact that Invokana causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute Invokana to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

149. Plaintiff reasonably relied on Defendants' representations and suffered injuries as a proximate result of that reliance.

150. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare.

Count Five – Breach of Express Warranty

151. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

152. At all relevant times, Defendants expressly represented and warranted to Plaintiff and Plaintiff's physicians and health care providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians, medical patients and the general public, that Invokana was safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was efficacious.

153. In particular, the "Warnings and Precautions" section of the Invokana prescribing information purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about.

154. In particular, the Consumer Medication Guide expressly indicates "What is the most important information I should know about INVOKANA?" and "What are the possible side effects of INVOKANA?" and "General information about the safe and effective use of INVOKANA" and does not mention that Invokana has been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events.

155. Furthermore, Defendants J&J, Janssen, Janssen R&D, Janssen Ortho, Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug Invokana was generally well tolerated and safe for use, and was not likely to cause side effects other than the ones listed—these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, bone fractures, etc.

156. Plaintiff's physician prescribed Invokana and Plaintiff purchased and consumed Invokana reasonably relying upon these warranties; Plaintiff and Plaintiff's physicians did not know and could not have learned independently that Defendants' representations were false and misleading.

157. Defendants knew and expected or should have known and expected, and intended Plaintiff to rely on their warranties.

158. The representations contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

159. In utilizing Invokana, Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of Defendants.

160. These warranties and representations were false in that Invokana is not safe, effective, fit and proper for its intended use because of its propensity to cause, among other conditions, diabetic ketoacidosis, kidney failure, and cardiovascular problems.

161. Because Invokana did not conform to Defendants' express representation, Defendants breached the warranties.

162. As a foreseeable, direct, and proximate result of the breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Six – Breach of Implied Warranty

163. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

164. At all relevant times, Defendants implied to Plaintiff and Plaintiff's physicians and health care providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians, medical patients and the general public, that Invokana was safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was efficacious.

165. In particular, the "Warnings and Precautions" section of the Invokana prescribing information implies that it fully describes the relevant and material potential side-effects that Defendants knew or should have known about.

166. In particular, the Consumer Medication Guide implies by omission in the sections entitled "What is the most important information I should know about INVOKANA?" and "What are the possible side effects of INVOKANA?" and "General information about the safe and effective use of INVOKANA" that Invokana has not been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events.

167. Plaintiff's physician prescribed Invokana and Plaintiff purchased and consumed Invokana reasonably relying upon these warranties, and Plaintiff and Plaintiff's physicians did not know and could not have learned independently that Defendants' representations were false

and misleading.

168. Defendants know or should have known and expected or should have expected, and intended Plaintiff to rely on their warranties.

169. The representations contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

170. In utilizing Invokana, Plaintiff reasonably relied on the skill, judgment, representations, and foregoing implied warranties of Defendants.

171. These warranties and representations were false in that Invokana is not safe, effective, fit and proper for its intended use because of its propensity to cause, among other conditions, diabetic ketoacidosis, kidney failure, and cardiovascular problems.

172. Because Invokana did not conform to Defendants' representation, Defendants breached the implied warranties.

173. As a foreseeable, direct, and proximate result of the breach of warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Seven – Fraudulent Misrepresentation

174. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

175. Defendants, both individually and in concert with one another, intentionally andfraudulently misrepresented the safety and efficacy of Invokana in the product label and through their marketing activities.

176. In particular, Defendants intentionally and fraudulently:

a. Failed to adequately warn about the risk of diabetic ketoacidosis;

b. Failed to provide full and complete information about Invokana to the FDA;

c. Provided a product label to Plaintiff's physicians that did not adequately disclose the risks that Defendants knew of;

d. Provided consumer information that did not adequately disclose the risks that Defendants knew of;

e. Overstated the benefits of Invokana; and

f. Marketed Invokana for unapproved uses such as weight loss and lowering blood pressure.

177. Furthermore, Defendants J&J, Janssen, Janssen R&D, Janssen Ortho, Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug Invokana was generally well tolerated and safe for use, and was not likely to cause side effects other than the ones listed—these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, bone fractures, etc.

178. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them, in willful, wanton, and reckless disregard for the lack of truthfulness of the representations and with the intent to defraud and deceive Plaintiff and Plaintiff's physicians.

179. Plaintiff and Plaintiff's physicians reasonably relied on the fraudulent misrepresentations both as communicated to them directly from Defendants and as communicated to them by others exposed to Defendants' pervasive marketing campaigns.

Count Eight – Negligent Misrepresentation

180. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

181. From the time Invokana was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and health care providers, and the general public, including but not limited to the misrepresentation that Invokana was safe, fit, and effective for human consumption.

182. Defendants owed a duty to Plaintiff to exercise reasonable care to ensure they did not misrepresent the safety or efficacy of Invokana nor create unreasonable risks of injury to others, and failed to exercise that reasonable care and therefore breached their duty.

183. The Defendants made the foregoing misrepresentations without any reasonable grounds for believing them to be true, and were, in fact, reckless.

184. The Defendants had a duty to correct these material misstatements because they knew or should have known that they were inaccurate and that others would reasonably rely on them and suffer injuries.

185. These misrepresentations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

186. The representations by the Defendants were in fact false, in that Invokana is not safe, fit and effective for human consumption, using Invokana is hazardous to health, and Invokana has a serious propensity to cause serious injuries to users, including but not limited to

the injuries suffered by Plaintiff.

187. The foregoing representations by Defendants were made with the expectation and intention of inducing reliance upon them and increasing the prescription, purchase and use of Invokana.

188. Plaintiff reasonably relied on the misrepresentations made by the Defendant to her detriment.

189. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Invokana.

190. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Invokana.

191. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

192. As a direct, proximate, and foreseeable result of Defendants' negligent misrepresentations, Plaintiff suffered injuries and damages as alleged herein.

Count Nine – Fraudulent Concealment

193. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

194. At all relevant times, Defendants knew that Invokana was defective, unreasonably unsafe, and that its risks were understated and its benefits were overstated.

195. Defendants willfully, intentionally and fraudulently concealed their knowledge of this from Plaintiff, Plaintiff's physicians, and the public, and instead knowingly provided false information.

196. Defendants withheld information that they had a duty to disclose through Invokana's labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Invokana was safe and effective.

197. Defendants withheld information about the severity of the substantial risks of using Invokana and their knowledge of the safety signals regarding adverse effects of Invokana.

198. Defendants withheld information that Invokana was not safer or more effective than alternative diabetes medications available on the market.

199. The above facts were material would have been considered important to a reasonable person.

200. Had the above facts been disclosed, they would have changed Plaintiff's decision to take Invokana and Plaintiff's physician's decision to prescribe it.

201. Defendants had a duty to disclose this information to Plaintiff and Plaintiff's physicians.

202. Defendants had sole access to material facts concerning, and unique and special knowledge and expertise regarding, the dangers and unreasonable risks of Invokana.

203. Defendants knew or should have known and expected or should have expected and intended that Plaintiff and Plaintiff's physicians rely on the inaccurate information they provided.

204. As a foreseeable, direct, and proximate result of Defendants' actions and fraudulent concealment, Plaintiff suffered injuries.

Count Ten – Fraud

205. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

206. Defendants' intentional misrepresentations and concealments constitute fraud under state law and were made with the intent to defraud physicians and consumers, including Plaintiff and Plaintiff's physicians.

207. Specifically, Defendants intentionally and fraudulently did the following:

a. Provided a "Warnings and Precautions" section of the Invokana prescribing information that purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about, but in which material and relevant information was fraudulently withheld from this section;

b. Provided Consumer Medication Guide that expressly indicates "What is the most important information I should know about INVOKANA?" and "What are the possible side effects of INVOKANA?" and "General information about the safe and effective use of INVOKANA" and fraudulently omits information that Invokana has been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events;

c. On information and belief, each and every advertisement and marketing channel fraudulently omits information about the risks of Invokana and overstates the benefits;

d. Failed to disclose that Invokana was not as safe and effective as other diabetes drugs;

e. Failed to disclose that Invokana does not result in safe and more effective diabetes treatments than other available drugs;

f. Failed to disclose that the risk of harm associated with Invokana was greater

than the risk of harm associated with other diabetes drugs;

g. Failed to disclose that Defendants knew that Invokana was not adequately tested;

h. Failed to disclose that testing had revealed unreasonably high risk of injury;

i. On information and belief, failed to disclose that Defendants intentionally withheld safety information from the FDA; and

j. Affirmatively asserted that Invokana was safe and effective.

208. Furthermore, Defendants J&J, Janssen, Janssen R&D, Janssen Ortho, Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug Invokana was generally well tolerated and safe for use, and was not likely to cause side effects other than the ones listed—these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, bone fractures, etc.

209. Each Defendant made the fraudulent statements to the public, generally, at numerous times throughout the marketing of Invokana, both individually, and in concert with each other.

210. The number and extent of fraudulent marketing communications are too numerous to list and are so pervasive that they fraudulently influence healthcare providers and consumers even without direct exposure to the marketing information because, as intended by Defendants, others hear the fraudulent communications and come to believe them and communicate to others that Invokana is safe and effective.

211. Plaintiff and Plaintiff's healthcare providers were exposed to the product label and medication guide and the fraudulently inaccurate information described above.

212. Defendants had access to these facts, while Plaintiff and Plaintiff's physicians did not and were unaware of them and could not reasonably learn of them from an alternative source.

213. The above facts were material to Plaintiff and Plaintiff's physician's decision to use and prescribe Invokana, and they reasonably relied on Defendants' representations.

214. As a direct, proximate, and foreseeable result of Defendants' fraud, they caused Plaintiff's injuries.

Count Eleven – Unjust Enrichment

215. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

216. Plaintiff conferred a benefit on Defendants by purchasing Invokana.

217. Plaintiff did not receive a safe and effective drug for which they paid.

218. It would be inequitable for the Defendants to retain this money because Plaintiff did not, in fact, receive a safe and efficacious drug.

219. By virtue of the conscious wrongdoing alleged in this Amended Complaint, Defendants have been unjustly enriched at the expense of Plaintiff, who hereby seeks the disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

Count Twelve – Violation of State Unfair Trade Practices and Consumer Protection Laws

220. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

221. Invokana is a product pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code § 47-18-101 *et seq*., and other applicable state consumer protection statutes (the "Acts").

222. Defendants knew, or should have known Invokana was defective in design and manufacture and its use created the risk of causing serious and life threatening injuries in patients, yet, Defendants knowingly, willfully, and intentionally failed to inform and warn the medical community and the consuming public, including Plaintiff, of these risks.

223. In violation of the Acts, Defendants engaged in deception, fraud, false pretense, false promise, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts regarding the risk of harm associated with the use of Invokana, with the intent that others rely upon such concealment, suppression, or omission, in connection with its sale or advertisement. Defendants omitted and concealed material facts from Plaintiff and Plaintiff's physicians and healthcare providers in product packaging, labeling, medical advertising, and promotional campaigns and materials, regarding the safety and use Invokana. Moreover, Defendants downplayed and understated the serious nature of the risks and dangers associated with the use of Invokana to increase their sales, to reap millions of dollars in profits from sales of their products, and to secure a greater market share.

224. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, healthcare providers, and consumers, including Plaintiff, would rely on the Defendants' false and deceptive statements and omissions.

225. Plaintiff's physicians and healthcare providers prescribed Invokana to Plaintiff, who suffered ascertainable losses of money and property as a result of Defendants' fraudulent methods, acts, practices, and sale of Invokana.

226. Defendants' promotion and release Invokana into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others, including Plaintiff, would rely upon such concealment, suppression, or omission in connection with the sale or advertisement of such merchandise or services by Defendants, in violation of the Acts.

227. Defendants concealed, omitted, and/or minimized the risk of serious and harmful side effects of Invokana, and/or provided misinformation about adverse reactions, risks, and potential harm from the use of Invokana, and succeeded in persuading physicians to prescribe it despite Defendants' knowledge that it was, and is, unreasonably dangerous and of the risk of adverse health effects connected with Invokana, as described in this Amended Complaint.

228. Defendants' practice of promoting and marketing Invokana created and reinforced the false impression as to the safety of Invokana, thereby placing consumers at serious risk of potential lethal side effects from use of the drug.

229. Defendants violated their duty to warn, post-manufacture, of the injurious and sometimes fatal side effects that arose when Defendants knew, or with reasonable care should have known, that Invokana was injurious and sometimes fatal to consumers.

230. Defendants intended, at the time Plaintiff's healthcare providers prescribed Invokana, that physicians and ultimately consumers, would reasonably rely upon the concealment, suppression, or omission by Defendants' officers, directors, agents, employees, principals, and representatives of the risks connected with the use of Invokana.

231. Defendants' actions in connection with manufacturing, distributing, and marketing Invokana evidence a lack of good faith, the failure of honesty in fact, and failure of

observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the Acts.

232. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference for the health, safety, and well-being of the consumers of Invokana when committing the above-described acts of consumer fraud. As a foreseeable, direct, and proximate result of Defendants' fraud upon the consumers of Invokana, Plaintiff's healthcare providers prescribed (and Plaintiff and Plaintiff's insurance company, were billed for) an unreasonably dangerous and unsafe product and incurred monetary damages and expenses.

233. As a proximate result of Defendants' acts and omissions and Plaintiff's ingestion of Invokana, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses.

Punitive Damages Allegations

234. Plaintiff adopts by reference each and every paragraph of this Amended Complaint as if fully copied and set forth at length herein.

235. The acts, conduct, and omissions of Defendants, as alleged throughout this Amended Complaint, were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Invokana users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Invokana. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

236. Prior to the manufacturing, sale, and distribution of Invokana, Defendants knew that the drug was in a defective condition as previously described and knew that those who were

prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Invokana.

237. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Invokana and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Invokana. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Invokana knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff and other consumers, entitling Plaintiff to exemplary damages.

II. PRAYER

238. **WHEREFORE,** Plaintiff prays for judgment against the Defendants, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

a. General damages in an amount that will conform to proof at time of trial;

b. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

c. Loss of earnings and impaired earning capacity according to proof at the time of

trial;

d. Medical expenses, past and future, according to proof at the time of trial;

e. Past and future mental and emotional distress, according to proof;

f. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

g. Punitive or exemplary damages according to proof;

h. Restitution, disgorgement of profits, and other equitable relief;

i. Injunctive relief;

j. Attorney's fees;

k. Costs of suit incurred herein;

l. Pre-judgment interest as provided by law; and

m. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

239. Plaintiff hereby demands a jury trial on all claims so triable in this action.

Date: October 14, 2016

Respectfully submitted,

/s/ Justin Gilbert

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CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2016, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Justin Gilbert
Justin Gilbert